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Left on Our Own: COVID-19, TRIPS-Plus Free Trade Agreements, and the Doha Declaration on TRIPS and Public Health

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SOUTH CENTRE

RESEARCH PAPER

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ABSTRACT

The cusp of the twentieth anniversary of the WTO Doha Declaration on the TRIPS Agreement and Public Health (hereafter “the Declaration”) was marked by a global pandemic. The Declaration and its iteration in the Agreement on Trade Related Aspects of Intellectual Property Rights (hereafter “TRIPS”) Article 31 bis, should have helped to contain the devastation in least developed and developing countries. The reality is that the pandemic is still ongoing, and the Global South led by South Africa and India are seeking a waiver of provisions to the TRIPS Agreement to ensure that COVID-19 therapeutics, diagnostics, and vaccines reach their citizens in order to contain the spread of the COVID-19 virus (“the TRIPS waiver”). These citizens are especially vulnerable because of their inability to access vaccines due to their prices and supply shortages caused by the refusal to share manufacturing technology. The Doha Declaration aimed at reaffirming the interpretation and implementation of the TRIPS Agreement to support WTO members’ right to protect public health and promote access to medicines. However, the operationalization of the Declaration via Article 31bis of TRIPS has been cumbersome and procedurally difficult to navigate. This paper argues that the current iteration of the Doha Declaration within TRIPS fails to meet the objectives of the Declaration as demonstrated by the need for a further waiver of the TRIPS agreement. It also attempts to “reimagine” Article 31 bis in light of the TRIPS waiver from the position of the Global South to make it more equitable and practicable and maintain the spirit of the Declaration.

La veille du vingtième anniversaire de la Déclaration de Doha de l'OMC sur l'Accord sur les ADPIC et la santé publique (ci-après "la Déclaration") a été marquée par une pandémie mondiale. La Déclaration et son itération dans l'Article 31 bis de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ci-après "ADPIC") auraient dû permettre de contenir les ravages dans les pays les moins avancés et en développement. La réalité est que la pandémie est toujours en cours, et que les pays du Sud, menés par l'Afrique du Sud et l'Inde, cherchent à obtenir une dérogation aux dispositions de l'Accord sur les ADPIC pour s'assurer que les produits thérapeutiques, les diagnostics et les vaccins contre le COVID-19 parviennent à leurs citoyens afin de contenir la propagation du virus COVID-19 ("la dérogation ADPIC"). Les citoyens de ces pays sont particulièrement vulnérables en raison de l'impossibilité d'accéder aux vaccins à cause de leur prix et des pénuries d'approvisionnement dues au refus de partager les technologies de fabrication. La Déclaration de Doha visait à réaffirmer l'interprétation et la mise en œuvre de l'Accord sur les ADPIC afin de soutenir le droit des membres de l'OMC à protéger la santé publique et à promouvoir l'accès aux médicaments. Cependant, l'opérationnalisation de la Déclaration par le biais de l'article 31bis de l'Accord sur les ADPIC a été laborieuse et difficile à gérer sur le plan procédural. Ce document soutient que l'itération actuelle de la Déclaration de Doha dans le cadre de l'Accord sur les ADPIC ne répond pas aux objectifs de la Déclaration, ce qui est démontré par la nécessité d'une nouvelle dérogation à l'Accord sur les ADPIC. Il tente également de "réimaginer" l'article 31 bis dans la perspective de la dérogation à l'accord sur les ADPIC, du point de vue des pays du Sud, pour le rendre plus équitable et plus pratique et préserver l'esprit de la Déclaration.

La cúspide del vigésimo aniversario de la Declaración de Doha de la OMC sobre el Acuerdo de los ADPIC y la Salud Pública (en adelante "la Declaración") estuvo marcada por una pandemia mundial. La Declaración y su iteración en el Artículo 31 bis del Acuerdo sobre los

Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (en adelante "ADPIC") deberían haber ayudado a contener la devastación en los países menos desarrollados y en desarrollo. La realidad es que la pandemia todavía está en curso, y el Sur Global, liderado por Sudáfrica e India, está buscando una exención de las disposiciones del Acuerdo sobre los ADPIC para asegurar que las terapias, diagnósticos y vacunas contra el COVID-19 lleguen a sus ciudadanos con el fin de contener la propagación del virus del COVID-19 (la "exención de los ADPIC"). Estos ciudadanos son especialmente vulnerables debido a la imposibilidad de acceder a las vacunas por su precio y a la escasez de suministro por la negativa a compartir la tecnología de fabricación. La Declaración de Doha pretendía reafirmar la interpretación y aplicación del Acuerdo sobre los ADPIC para apoyar el derecho de los miembros de la OMC a proteger la salud pública y promover el acceso a los medicamentos. Sin embargo, la puesta en práctica de la Declaración a través del artículo 31bis del ADPIC ha sido engorrosa y de difícil procedimiento. Este documento argumenta que la actual iteración de la Declaración de Doha dentro del ADPIC no cumple los objetivos de la Declaración, como demuestra la necesidad de una nueva exención del acuerdo ADPIC. También intenta "reimaginar" el artículo 31 bis a la luz de la exención de los ADPIC desde la posición del Sur Global para hacerlo más equitativo y practicable y mantener el espíritu de la Declaración.

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1. INTRODUCTION

November 2021 marked the twentieth anniversary of the World Trade Organization (WTO) Ministerial Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)[1] and Public Health[2] ("the Doha Declaration"). During this time, the world was also in the second year of a global pandemic due to the spread of COVID-19. Trade policy experts, intellectual property specialists, and public health experts from the Global South found themselves in a position similar to what they experienced prior to the adoption of the Doha Declaration, with India and South Africa leading the clarion cry once again for the members of the WTO from developed countries to agree to suspend intellectual property rights (IPRs) in order to save lives. The Doha Declaration was not sufficient to mitigate the threat, both real and potential, of COVID-19. The COVID-19 Vaccines Global Access (COVAX) was set up as a multilateral initiative co-led by the Centre for Epidemic Preparedness Innovations (CEPI), GAVI Vaccine Alliance, and the World Health Organization as a global mechanism for pooled procurement to ensure fair and equitable access to COVID-19 vaccines.[3] This initiative was able to channel just 311 million doses to 143 countries in need as at 29 September 2021.[4] In contrast, 6.1 billion vaccine doses have been delivered worldwide, mostly to developed countries.[5] This illustrates the gap in access to medicines that still persists twenty years after the Doha Declaration.

This paper provides an overview of article 31*bis* of TRIPS and of the objectives of the Doha Declaration within the context of the call for a TRIPS waiver. It gives an overview of the need for the waiver amidst the existence of the Doha Declaration. It examines the effect of TRIPS-plus provisions in Free Trade Agreements (FTAs) on the use of the flexibilities confirmed by the Declaration using Kenya and the proposed United States-Kenya Free Trade Agreement (USKEFTA) as the focus. It then provides recommendations for developing and least developed countries in negotiating such agreements in a way that would maintain the spirit of the Declaration.

The paper begins by providing the background to article 31*bis,* pointing out the aims of the Doha Declaration, and illustrating the difficulty in the use of that article. Next, the paper investigates the resistance from the Global North to the TRIPS waiver request amidst the advent of TRIPS-plus provisions in bilateral agreements with the USKEFTA as a case study. The paper then considers how article 31*bis* can be "reimagined". Finally, the paper concludes with some recommendations that Kenya and other developing and least developed countries ought to consider when negotiating FTAs in order to maintain the spirit of the Doha Declaration.

[1] World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property Rights, 1869 U.N.T.S 299, (1994).
[2] Doha Declaration on the TRIPS Agreement and Public Health, 14 November 2001.
[3] Karen Hussman, "Global access to Covid-19 vaccines: Lifting the veil of opacity", U4 Issue 2021:12, (Bergen, Norway, Chr. Michelsen Institute). Available from https://reliefweb.int/sites/reliefweb.int/files/resources/lifting-the-veil-of-opacity-in-covid-19-vaccines-to-combat-the-pandemic.pdf.
[4] Ibid.
[5] Ibid.

2. TRIPS ARTICLE 31*BIS*, THE OBJECTIVES OF THE DOHA DECLARATION AND THE CURRENT CALL FOR A COVID-19 TRIPS WAIVER

a) Background to TRIPS and Article 31

TRIPS was enacted in 1995 under the WTO and is the main agreement that covers intellectual property rights (IPRs) in the international arena. It establishes a multilateral framework of minimum standards whereby all Member States are required to fulfil a specific set of obligations as members of the WTO relating to issues of intellectual property protection. This section focuses on article 31 and the problems associated with its application that culminated in the Doha Declaration and subsequent amendment to TRIPS.

Article 31 of the Agreement deals with the use of patented subject matter without the authorization of the right holder, or "other use" which is defined in the accompanying footnote to the text of the provision as "use other than that allowed under Article 30".[6] This provision is one of the flexibilities enabled by TRIPS and generally covers use of patented subject matter by a government or authorized third parties: it is the compulsory licensing provision of TRIPS whose additional provisions indicate how and when compulsory licenses can be issued.[7]

Compulsory licensing is one of the flexibilities afforded by TRIPS whereby a government allows persons to produce a patented product or process without the consent of the rights-holder.[8] This flexibility is of particular importance to developing countries as, inter alia, it can promote access to medicines.[9] As pharmaceuticals are often thought of as enjoying elevated status as a public health good, compulsory licensing provides an alternative route for countries to produce or import the required pharmaceuticals for the net benefit of their citizens without violating the patent holders' IPRs.[10]

While the compulsory licensing mechanism under article 31 provided a potential solution to developing and least-developed countries in need of essential medicines, articles 31(f) and 31(h) proved to be problematic provisions in utilizing this flexibility. Article 31(f) provided that the use of the subject matter for which a compulsory license had been issued may only be for predominantly supplying the domestic market.[11] This meant that if a compulsory license were granted by a country with manufacturing capabilities only to export a pharmaceutical product to another country, it would be in violation of article 31(f). Article 31(h) presented a different problem whereby the patent holder is entitled to "adequate remuneration", accounting for the "economic value of the authorization".[12] This highlighted a strain in the ability of developing and least-developed countries to not only pay for the use, but to

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[6] World Trade Organisation, Agreement on Trade Related Aspects of Intellectual of Property Rights, 1869 U.N.T.S 299, art. 31 (1994).
[7] World Trade Organisation, "Compulsory licensing of pharmaceuticals and TRIPS". Available from https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.
[8] World Trade Organization, "Compulsory licensing of pharmaceuticals and TRIPS". Available from https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.
[9] Sisule F. Musungu, Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they promote access to medicines?* (Geneva, South Centre, 2006) South Perspectives Series. Available from https://apps.who.int/iris/bitstream/handle/10665/43503/9291620327_eng.pdf?sequence=1&isAllowed=y.
[10] Nicholas G. Vincent, "TRIP-ing Up: The Failure of TRIPS Article 31*bis*" *Gonzaga Journal of International Law*, vol. 24: 1 (2020).
[11] WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, 1869 U.N.T.S 299, art. 31(f) (1994).
[12] WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, 1869 U.N.T.S 299, art. 31(h) (1994).

determine the appropriate "economic value of the authorization". Articles 31(f) and 31(h) jointly underscored problematic aspects of compulsory licensing.[13]

b) The Doha Declaration: Background and Aims

In 2001, precipitated by the HIV/AIDS epidemic, the WTO Ministerial Conference adopted the Doha Declaration with the purpose of affirming the flexibilities available to members of the WTO seeking to protect public health. Generally, the Declaration focused on the "gravity of the public health problems afflicting many developing and least-developed countries."[14] The driving force behind the eventual inclusion of article 31*bis* was Paragraph 6 of the Doha Declaration which recognized that "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and report to the General Council before the end of 2002".[15] The core aim of the Declaration was therefore to assert that safeguards on IPRs could be implemented for public health purposes without being in violation of TRIPS, and the Council for TRIPS was called upon to devise a workable mechanism to give effect to this.

The Declaration also affirmed that TRIPS should be interpreted and implemented to protect and promote public health and access to medicines for all, and it was indicative of the power of developing countries to "drive through an agenda in the interest of public health" that was perceived as antithetical to the interests of drug companies and developed countries.[16]

c) Implementation of Paragraph 6 of the Doha Declaration in TRIPS via Article 31bis

The text of Paragraph 6 resulted in the adoption of a Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in 2003, which provided temporary waivers to Articles 31(f) and 31(h).[17] The waivers' duration was contingent on annual reviews and an amendment of TRIPS via what later emerged as article 31*bis.*[18] These waivers enabled by Paragraph 6 were aimed at addressing the shortcomings of the TRIPS Agreement, specifically those highlighted above in article 31.[19] This meant that countries without manufacturing capabilities could benefit from compulsory licenses issued in countries that had previously been unable to produce pharmaceutical products only for export to developing and least-developed countries in need, without violating TRIPS. Additionally, the waiver of article 31(h) exempted resource-poor countries from having to remunerate patent owners for the pharmaceutical products imported under the license.

In 2005, the WTO General Council adopted a Decision on the Amendment of the TRIPS Agreement to make the waivers permanent. The Doha Declaration, hence, triggered what eventually became article 31*bis* of TRIPS in 2017, the first and (to date) only amendment to the Agreement. Under article 31*bis*, a country in need of a particular pharmaceutical product,

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[13] Susan K. Sell, "TRIPS and the Access to Medicines Campaign", *Wisconsin International Law Journal*, vol. 20, issue 3 (2001).
[14] WTO, Declaration on the TRIPS Agreement and Public Health, WTO Doc.WT/MIN(01)/DEC/2, para. 1, (2002).
[15] WTO, Declaration on the TRIPS Agreement and Public Health, WTO Doc.WT/MIN(01)/DEC/2, para. 6 (2002).
[16] Sharon Friel, "Global health disruptors: Doha Declaration" 28 November 2018 Available from https://blogs.bmj.com/bmj/2018/11/28/global-health-disruptors-doha-declaration/.
[17] Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/L/540, (2003).
[18] Jerome H. Reichman, "Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options", *Journal of Law, Medicine and Ethics* vol. 37, (2009).
[19] Nicholas G. Vincent, "TRIP-ing Up: The Failure of TRIPS Article 31*bis*" *Gonzaga Journal of International Law*, vol. 24: 1 (2020).

but lacking or with insufficient manufacturing capabilities to produce it, is able to import the product under a compulsory license from a producing country without violating the referred to provisions found in the Agreement.[20] Although this new framework was expected to be used widely, it has never been used; it had only been used once before the amendment was introduced.[21]

d) Scope and Utility of Article 31bis: The Necessity of a Further Waiver

The first paragraph of article 31*bis* seeks to alleviate the problem created in article 31(f) by providing that, in certain circumstances, Member's obligations under article 31(f) "shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)".[22] The second paragraph makes the waiver to article 31(h) permanent by providing that "adequate remuneration pursuant to article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member".[23] This paragraph dually functions to ensure that the patent owner is compensated, but not twice, and also that the resource-poor recipient is not burdened with costs they could not afford.[24] Paragraph 3 is focused on "harnessing economies of scale" by enabling WTO members that are party to regional trade agreements to bypass the obligation under article 31(f) to the extent necessary that will "enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question".[25] The fourth paragraph is a non-violation provision that prevents Members from challenging any measure taken under article 31*bis* as being in violation of GATT Article XXIII 1(b) and 1(c).[26] The fifth paragraph lays emphasis on conserving all the extant flexibilities under TRIPS in stating that 31*bis* and the Annex to the Agreement "are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this agreement other that paragraphs (f) and (h) of Article 31".[27]

Collectively these five paragraphs operate to mitigate the deficiencies of articles 31(f) and 31(h), however the administrative burden and difficulty of using article 31*bis* meant it has largely gone unused. To date, Canada has been the only country to successfully use the

[20] WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, 1869 U.N.T.S 299, article 31*bis*, (1994).
[21] The system created by the 2003 waiver was only used once for the export by a Canadian firm, Apotex, of a combination of antiretrovirals to Rwanda. Once the procedural requirements were met which would allow Rwanda to import 260,00 packs of medication to treat HIV/AIDS, the process began to reveal issues that likely discouraged other countries from using the framework. For instance, it took nearly three years for Rwanda to receive the full shipment of drugs that it had requested under the waiver. The framework has not been used since, owing in part to the perceived delays which in the full process. See Nicholas G. Vincent, "TRIP-ing Up: The Failure of TRIPS Article 31bis" Gonzaga Journal of International Law, vol. 24: 1 (2020), and Carlos M. Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", Policy Brief No. 57 (South Centre, January 2019). Available from https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf.
[22] Ibid.
[23] Ibid.
[24] Nicholas G. Vincent, "TRIP-ing Up: The Failure of TRIPS Article 31*bis*" *Gonzaga Journal of International Law*, vol. 24, Issue 1 (2020).
[25] This only applies, however, if at least half of the members of a regional trade agreement are least developed countries. WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, 1869 U.N.T.S 299, article 31*bis*, (1994).
[26] WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, 1869 U.N.T.S 299, article 31*bis*, (1994).
[27] WTO, Agreement on Trade Related Aspects of Intellectual Property Rights, 1869 U.N.T.S 299, article 31*bis*, (1994).

compulsory licensing mechanism under the waiver later incorporated as article 31*bis* in the provision of generic AIDS medicine to Rwanda.[28] Their use of the waiver was accompanied by significant problems such as the complexity of the process whereby the waiver proved too cumbersome in its application resulting in an over four year long process and huge costs needed to get the medication to Rwanda.[29]

A recent attempt at utilising 31*bis* in 2021 was put forward by Bolivia during the current COVID-19 pandemic. Bolivia, being a developing nation facing the challenges of poverty, inequality, precarious work conditions, and a weak healthcare system, was underprepared for a health emergency.[30] Combined with the strain that COVID-19 placed on the healthcare system and economy, Bolivia had staggeringly low rates of vaccination as doses came into the country too slowly.[31] As the country lacked the manufacturing capacity to produce its own vaccines, one of the policy options it had at its disposal was to make use of compulsory licensing under 31*bis.* Bolivia self-identified as a country wishing to purchase COVID-19 vaccines from Biolyse Pharma, a Canada based manufacturer of sterile injectable medicine, and made a general notification to the WTO in February 2021, intending to purchase 15 million doses of COVID-19 vaccines from Biolyse Pharma subject to the grant of a voluntary license by Johnson & Johnson (J&J, the patent holder), or grant of an export-oriented compulsory license under the Canadian Access to Medicine Regime (CAMR) system.[32]

On 3 March 2021, Biolyse Pharma wrote to J&J to request a voluntary license to manufacture and sell their COVID-19 vaccine in Canada and export it to WTO Members under 31*bis*.[33] J&J refused to negotiate and rejected the request.[34] This meant Biolyse had to alternately seek a compulsory license under CAMR, which was fraught with bureaucratic challenges and uncertainties that left Biolyse with no clear answers on how to initiate and pursue the process.[35] The protracted process, which has not resulted in a license at the date

[28] Donald Harris, "TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing" *Journal of Intellectual Property Law*, vol. 18, Issue 2 (March 2011).

[29] The lengthy delay was in part due to the two years of negotiations between Apotex (the manufacturer of the drugs) and the patent holders. See Donald Harris, "TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing" *Journal of Intellectual Property Law*, vol. 18, Issue 2 (March 2011).

[30] Calla Hummel and others, "Poverty, precarious work, and the COVID-19 pandemic: Lessons from Bolivia", The *Lancet*, vol. 9, No. 5 (May 2021), available from https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00001-2/fulltext.

[31] Helen Lock, "Bolivia Could Unlock New Access to Life-Saving COVID-19 Vaccines - But Needs Canada to Grant a License", Global Citizen, 2 August 2021. Available from https://www.globalcitizen.org/en/content/bolivia-canada-patents-covid-19-vaccines-trips/ (accessed 20 March 2022).

[32] Muhammad Zaheer Abbas, *Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case*, Research Paper 136 (Geneva, South Centre, 2021). Available from https://www.southcentre.int/wp-content/uploads/2021/09/RP136_Canadas-Political-Choices-Restrain-Vaccine-Equity-The-Bolivia-Biolyse-Case_EN-1.pdf.

[33] Ibid.

[34] Zachary Brennan, "How to manufacture COVID-19 vaccines without the help of J&J, Pfizer or Moderna? Biolyse sees the difficulties up close" 17 May 2021. Available from https://endpts.com/how-to-manufacture-covid-19-vaccines-without-the-help-of-jj-pfizer-or-moderna-biolyse-sees-the-difficulties-up-close/ (accessed 22 March 2022).

[35] The first step under this regime is to get the medicine added to Schedule 1 which is a list of patented pharmaceutical products that are eligible for export under CAMR. Schedule 1 can be amended by the Governor in Council, with this regulatory step being further incumbent on the recommendation of the Minister of Innovation, Science and Industry, and the Minister of Health. Biolyse requested the Minister of Health and the Minister of Innovation, Science and Industry to recommend to the Governor in Council to add the COVID-19 vaccine to Schedule 1 of the Patent Act. Unfortunately, the process to amend Schedule 1 is rife with challenges and uncertainties, and when coupled with the Canadian government stonewalling of the process and not responding to Biolyse queries about adding the COVID-19 vaccine to the list, it left Biolyse with no clear answers on how to pursue the process. See Section 21.03(1), Patent Act (Canada, 1985), Muhammad Zaheer Abbas, "Canada's Political Choices Restrain Vaccine Equity: The Bolivia-Biolyse Case", (Geneva, Switzerland, South Centre, 2021) Research Paper 136. Available from https://www.southcentre.int/wp-content/uploads/2021/09/RP136_Canadas-Political-Choices-Restrain-Vaccine-Equity-The-Bolivia-Biolyse-Case_EN-1.pdf.

of writing this paper, ultimately exposed how existing mechanisms under TRIPS are not working as intended, including during a health emergency where their use was imperative.

All these factors taken together are indicative of the inherent failure of the solitary TRIPS amendment adopted so far: impractical at best, and pointless at worst. The inevitable outcome of the continued imposition of a multilateral IPRs regime that provided unworkable solutions to the problem of access to medicine for developing countries could only be these same countries seeking a further waiver when faced by a global pandemic. The paper will next address how the practicality problem with 31*bis* is magnified when viewed through resistance to the TRIPS Waiver and FTAs seeking TRIPS-plus provisions, which undercut the progress made in striking a balance between IPRs and access to medicines.

3. RESISTANCE TO THE TRIPS WAIVER AND SIMILARITIES OF ARGUMENTS WITH TRIPS-PLUS FTAS

a) Resistance to the Waiver

The proposed waiver from certain provisions of the TRIPS Agreement for the prevention, containment, and treatment of COVID-19 (TRIPS waiver),[36] more than a year after it was first tabled, faced opposition at the WTO majorly from the Global North.[37] The European Union, Norway, Canada and the United Kingdom were at the forefront in the resistance to the waiver.[38] This meant that a large majority of the world's population especially in the Global South remained unvaccinated while a number of variants of COVID-19 are now in circulation.[39]

There have been constant tensions within the WTO over the right balance between the protection of IPRs and access in low-income countries to urgently needed medicines.[40] The initial resistance to the waiver pointed towards concerns that IPRs would be undermined. The debate around the TRIPS waiver has been likened to the two decade-old tensions between developed and developing countries over compulsory licensing and generic medicine distribution of HIV/AIDS medicines.[41] Both debates, between the undermining of IPRs and equitable access to medicines are on one end of the spectrum referred to as a complication of the multilateral trading system whereby trade obstacles to public health become evident.[42] One fork of the resistance towards the TRIPS waiver was that it sought to solve an "unproven problem".[43] The argument is that there has been no evidence that IPRs are a genuine barrier for accessibility of COVID-19 related vaccines, medicines, and technologies.[44] Further, it has been argued that the TRIPS Agreement through Articles 8, 7, and 31*bis* has struck a balance between protecting IPRs and ensuring access to essential medicines.[45] There is however, discontent, especially amongst pharmaceutical companies, with regard to compulsory licensing in particular, which they view as a derogation from the

[36] World Trade Organization, TRIPS Council "Waiver from certain provisions of the TRIPs Agreement for the prevention, containment and treatment of COVID-19", IP/C/W/669, 2 October 2020. Available from https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True.

[37] Siva Thambisetty, "Opposition to the TRIPS waiver: dispatches from the frontline", LSE British Politics and Policy, 20 December 2021, Available from blogs.lse.ac.uk/politicsandpolicy/trips-waiver-one-year-on (accessed 6 January 2022). See also James Bacchus "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines" *Free Trade Bulletin* No. 78 (Cato Institute, 16 December 2020) <www.jstor.org/stable/resrep27669> (accessed 12 January 2022). Bacchus states that the waiver request raises a new the recurring debate within the WTO.

[38] Siva Thambisetty, "Opposition to the TRIPS waiver: dispatches from the frontline", LSE British Politics and Policy, 20 December 2021. Available from <blogs.lse.ac.uk/politicsandpolicy/trips-waiver-one-year-on/> (accessed 6 January 2022). Dr. Thambisetty further states that the waiver "remains moribund" more than a year after it was first raised.

[39] According to the World Health Organisation, as of January 2022 there are five known variants of COVID-19: Alpha, Beta, Gamma, Delta and Omicron. See https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/.

[40] James Bacchus "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines", *Free Trade Bulletin* No. 78 (Cato Institute, 16 December 2020). Available from <www.jstor.org/stable/resrep27669> (accessed 12 January 2022).

[41] Ibid.

[42] Ibid. Bacchus argues that "the last thing the WTO needs is another debate over perceived trade obstacles in public health".

[43] UK Mission to the WTO, UN, and Other International Organisations (Geneva). "UK Statement to the TRIPS Council: Item 15 Waiver proposal for COVID-19" UK Government, 16 October 2020. Where the UK's WTO Delegate described the waiver as "an extreme measure to address an unproven problem".

[44] Helen Collis "WTO Members reject IP rules waiver for coronavirus technologies" Politico Pro, 16 October 2020.

[45] James Bacchus "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines" *Free Trade Bulletin* No. 78 (Cato Institute, 16 December 2020). Available from <www.jstor.org/stable/resrep27669> (accessed 12 January 2022).

customary workings of "market based capitalism".[46] The second fork of the argument which makes up most of the resistance, is based on the premise that such a waiver would remove all incentives from pharmaceutical companies to produce essential pharmaceuticals and rather than enforce a waiver, the waiver should be approached on a voluntary basis.[47] This stems from a particular ideology of intellectual property (IP) which can be explained as follows: IP is revered as it is believed to be obtained from pure meritocracy and creativity, whereas in reality most inventions involve investment as well as good fortune. This ideology further perpetuates the understanding that IP is sacred, and its regulation is seen as an affront to the authority of property.[48] The above ideology has its origins in certain theories of IP; the proponents of the TRIPS waiver, however, can also find grounding in IP theories.

The proponents of the TRIPS waiver found grounding for their argument in the human rights approach and the public goods theories of IP. The human rights approach in this instance refers to the obligations of countries under certain international, regional, and national legal instruments.[49] There are at least five human rights provisions that apply in the context of the TRIPS Agreement and access to medicines.[50] The obligations that we are concerned with here relate to the right to health. Access to medicines is a fundamental element to the right to health.[51] However, the human rights approach to access to medicines has been described by those who resisted the waiver, as a "superficial moral appeal" which does not hold up as it does not meet the urgent public needs (that is, responding to pressing public needs during a pandemic or other global health emergency).[52] Yet the impact of IPRs on the right to health as a result of product patents and the high prices set by patentees is well documented,[53] as is the fact that it can create a shortage of supply to respond to an urgent global demand.[54] Further, it should be noted that access to medicines goes beyond the initial arguments around the Doha Declaration which were principally -but not exclusively- aimed at addressing the HIV/AIDS crisis.[55]

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[46] Ibid.

[47] Siva Thambisetty, "Opposition to the TRIPS waiver: dispatches from the frontline", *LSE British Politics and Policy*, 20 December 2021. Available from blogs.lse.ac.uk/politicsandpolicy/trips-waiver-one-year-on/ (accessed 6 January 2022). Dr. Thambisetty referred to this being a shared view of Health Officials in Germany and the UK.

[48] Siva Thambisetty, "Opposition to the TRIPS waiver: dispatches from the frontline", *LSE British Politics and Policy*, 20 December 2021. Available from blogs.lse.ac.uk/politicsandpolicy/trips-waiver-one-year-on/ (accessed 6 January 2022).

[49] These include the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, Conventions on the Rights of the Child, and the African Charter on Human and People's Rights. All these instruments cement the protection of the right to health and extend its reach to determinants such as nutrition, housing, access to safe water and sanitation, a healthy environment and safe and healthy working conditions.

[50] Paul O. Ogendi "Pharmaceutical trade policies and access to medicines in Kenya" *African Human Rights Law Journal*, vol. 19, No. 2 (2019), pp. 698-720. Paul Ogendi points out these five as the right to health, the right to life, the right to human dignity, the right to information and the right to public participation.

[51] Ibid.

[52] James Bacchus "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines", *Free Trade Bulletin* No. 78 (Cato Institute, 16 December 2020). Available from www.jstor.org/stable/resrep27669 (accessed 12 January 2022).

[53] Paul O. Ogendi "Pharmaceutical trade policies and access to medicines in Kenya" (2019) 19 *African Human Rights Law Journal*, vol. 19, No. 2 (2019), p. 704. Ogendi points out that the Special Rapporteur on the Right to Health published a report in 2009 on access to medicines and the right to health from an intellectual property perspective. The Special Rapporteur argued that in the interests of public health countries should be allowed to use the existing TRIPs flexibilities and noted that the existence of pressure imposed on developing countries by developed countries and multinational corporations (such as Big Pharma) in the context of utilizing TRIPs flexibilities.

[54] See, e.g., Carlos Correa "Expanding the production of COVID-19 vaccines to reach developing countries Lift the barriers to fight the pandemic in the Global South" Policy Brief 92, South Centre, April 2021. Available from https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf.

[55] Paul O. Ogendi "Pharmaceutical trade policies and access to medicines in Kenya", *African Human Rights Law Journal,* vol. 19, No. 2 (2019), p. 706. Ogendi argues that the clearest indication that the Human Rights Council broadened the scope of the right to health beyond access to ARVs to all medications in its June 2013 Resolution 23/14. See HRC Resolution 23/14, June 2013, Available from https://documents-dds-ny.un.org/doc/UNDOC/GEN/G13/150/49/PDF/G1315049.pdf?OpenElement (accessed 21 January 2022).

Where goods can be used without IP restrictions such that they are not exclusive to the inventor, they are referred to in economic terms as goods in the "public domain" or "public goods".[56] The argument by those who resisted the TRIPS waiver has been that the application of the public goods theory in order to meet the right to the highest attainable standard of health for all is myopic.[57] Further, that this view of essential medicines as a public good does not align with the fact that many medicines would not exist if not for IPRs and the protections that they afford.[58] In this vein, proponents of this view found IPRs as necessary exceptions to free trade and called, moreover, for enhanced IPRs.[59] Some arguments against the public goods theory application have suggested that government intervention could take the alternative form of subsidies for research and development of these public goods.[60] In fact, in the case of COVID-19 vaccines, most of the funding for the vaccines was obtained from public funds, namely from the contribution of taxpayers such that they are referred to as "the people's vaccine".[61] In this situation, it seemed then amply justified to ask for a waiver of IPRs.

b) The Development Theory of IP applied to the TRIPS-plus Provisions and Resistance to the TRIPS Waiver

Intellectual property as a means to socio-economic and technological development has been recognized as one of the emerging theories of intellectual property.[62] Proponents of the theory are of the view that the protection of intellectual property is only justified if society receives value equal to the rights granted. Further, the theory supports the view that intellectual property laws should be vehicles for economic growth and social development as well as the realization of human rights; consequently, they should be designed and implemented to reflect these values.[63] In the intellectual property context, development centers around human freedoms and capabilities to have basic economic needs fulfilled.[64] For developing and least developed countries, this theory is justified as it serves two functions. Firstly, it allows these countries to weigh the benefits of intellectual property rights against the burdens of these rights. Secondly, it also allows them to maximize opportunities

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[56] Kur A and Dreier T *European Intellectual Property Law: Text, Cases and Materials* (Cheltenham, Edward Elgar, 2013) p. 8.

[57] James Bacchus "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines", Free Trade Bulletin No. 78 (Cato Institute, 16 December 2020) Available from www.jstor.org/stable/resrep27669 (accessed 12 January 2022).

[58] Ibid.

[59] Ibid.

[60] Michael Spence *Intellectual Property* (Oxford University Press, Oxford, 2007) p.65. Spence labels the public good theory as "the Orthodox Argument" with roots mostly in the United States. The whole premise being that there needs to be a distinction between private and public goods as this distinction would indicate if there would be "deadweight losses" where an IP owner would have exclusive rights over a public good which they would consider a 'market failure'. This would lead to a lack of incentive to create. Spence also notes that this argument is politically powerful and is enshrined in the US Constitution at art 1, s 8, cl 8 which provides that Congress will have the power to promote these exclusive rights of IP creators. This goes a long way to explain the US approach to IP rights.

[61] Karen Hussman, "Global access to COVID-19 vaccines: Lifting the veil of opacity", U4 Issue 2021:12, (Bergen, Norway, Chr. Michelsen Institute) p.11. Available from https://reliefweb.int/sites/reliefweb.int/files/resources/lifting-the-veil-of-opacity-in-covid-19-vaccines-to-combat-the-pandemic.pdf. This is especially true for the AstraZeneca and Moderna vaccines.

[62] Akinyi Melissa Anne Omino, "Reconfiguring international pharmaceutical patent protection principles to combat linkage evergreening: 'De-linking the evergreen' and proposing a solution for developing countries", LLD Dissertation, University of Fort Hare, 2018 p. 37.

[63] Ibid. See also Oyewunmi A*, Nigerian Law of Intellectual Property* (Lagos, University of Lagos, 2015) p. 14.

[64] Amartya Sen, "What is the Role of Legal and Judicial Reform in the Development Process" Speech delivered at the first World Bank conference on Comprehensive Legal and Judicial Development, Washington, D.C., 5 June 2000. Available from https://issat.dcaf.ch/Learn/Resource-Library/Policy-and-Research-Papers/What-is-the-role-of-legal-and-judicial-reform-in-the-development-process (accessed 12 January 2022).

afforded by the flexibilities provided in international treaties to their advantage.[65] This theory would therefore align with the March 2011 Human Rights Council (HRC) Resolution 16/28[66] pertaining to the enforcement of IPRs. This HRC Resolution made a key addition noting that the Doha Declaration should at all times be taken into account while enforcing IPRs domestically.[67] This sets the stage for the application of the theory by developing countries when negotiating FTAs and considering their impact on the domestic IPR landscape and the realization of human rights. Any provisions that call for enhanced enforcement of IPRs and reduced requirements towards patentability will not bear fruit for the public interest or public health of citizens in developing and least developed countries. These citizens are importers of IP goods and licensees of IPRs, they will suffer the brunt of those policies amidst all the socio-economic issues that they face. Moreover, it joins in with the call for the TRIPS waiver. COVID-19 has had a great socio-economic impact in all countries especially those in the Global South. The TRIPS waiver would offer a reprieve to the situation by ensuring access to vaccines, treatments, and diagnostics. It is prudent then to look at how new FTAs are negotiated and how they would interact with the aims of the Doha Declaration. In order to do this, we take a look at the USKEFTA that was under negotiation at the time of drafting this paper.

c) The Kenyan Context: the Proposed USKEFTA and the Doha Declaration

FTAs are the current machinery that carry forward TRIPS-plus provisions sought by developed countries through to developing countries. The USKEFTA is an example. These agreements have developed a new, fragmented, trading system beyond the purviews of the WTO and the checks and balances that exist therein. The intention to enter into the USKEFTA was announced in February 2020, a month or two before a global lockdown due to the COVID-19 pandemic, and in July 2020 the Kenyan and US Governments formally begun negotiations.[68] It is important to understand the mechanisms of trade policy making in Kenya in order to realize the threat that this FTA poses to the public health and public interest of Kenya's citizens.

Kenyan trade policy has been stated to assume a perfect market without room for market failures.[69] This means that the country's trade policy does not make room for the identification of adverse impacts but only for potential benefits in relation to the trade measures it takes.[70] This is significant as the Kenyan trade policy development process, including in the area of IPRs, is coordinated at the Ministry of Industrialization, Trade and Enterprise Development (the Ministry of Trade) supported by the participation of other government departments.[71] Where such policies relate to international trade, the Ministry of Foreign Affairs and International Trade is also a coordinator as from 2017.[72] Human rights in

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[65] Oyewunmi A, *Nigerian Law of Intellectual Property* (Lagos, University of Lagos, 2015) p.14.
[66] HRC Resolution 16/28, March 2011, UN DOC A/HRC/Res/16/28 para 19.
[67] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya", *African Human Rights Law Journal*, vol. 19, No. 2 (2019), p. 705. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 (accessed 12 January 2022).
[68] https://ustr.gov/about-us/policy-offices/press-office/press-releases/2020/july/joint-statement-between-united-states-and-kenya-launch-negotiations-towards-free-trade-agreement.
[69] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya" (2019) 19 *African Human Rights Law Journal* p. 714. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 (accessed 12 January 2022).
[70] Ibid.
[71] Ibid. Ogendi notes that the Ministry of Health in Kenya has a very limited role to play in terms of ensuring access to medicines for Kenyan citizens, especially in relation to the adverse impact of pharmaceutical trade policies even as it stands to be most affected by such policies.
[72] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya" (2019) *African Human Rights Law Journal*, 19, p. 715. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 accessed 12 January 2022.

these policies have been reported to be introduced through specific trade instruments such as the African Growth and Opportunity Act (AGOA) and the Cotonou Agreement.[73] The fact that AGOA may not be renewed was also tabled as a reason why the Kenyan government was entering into negotiations with the US on the USKEFTA.[74] The Ministry of Trade has no internal mechanism to address human rights concerns in trade if it should be required.[75] Nevertheless, the Ministry of Trade did play a role in the integration of the TRIPS Agreement flexibilities under Kenya's Industrial Property Act (IPA), 2001.[76] This role was influenced by the fact that in 2001 the momentum was in favor of developing countries' approaches, since the Doha Declaration had also been adopted.[77]

Kenya was an advocate for the changes to article 31 that eventually resulted in article 31*bis*.[78] While Kenya has never utilized the compulsory licensing mechanism contained in article 31*bis*, there were notable hindrances regarding accessibility to affordable medication such as HIV/AIDS drugs. These included a lack of manufacturing capacity to produce the drugs, the presence of an "oligopolistic pharmaceutical sector"[79] in the country and firms' reluctance to process drugs under a compulsory license and, lastly, the fact that even non-patented HIV/AIDS drugs remained inaccessible.[80] Despite these problems, the Kenyan Government remained steadfast in its position that IPRs "should be exercised for the mutual benefit of rights holders and consumers".[81] In addition to putting pressure on the WTO via its participation in the African Group during the push for amendments to the compulsory licensing provisions under articles 31(h) and 31(f) of TRIPS, the Kenyan Government (including the Ministry of Health and the Ministry of Trade) and the Kenyan Industrial Property Office (KIPO, as it was then known) played major roles in the discussion on public health and patents.[82] Prioritizing and advising on the reform of patent law by KIPO secured the enactment of the IPA's provision on compulsory licensing.[83]

The Attorney General's Office through its Treaty Department ensures that the legal limits are observed in relation to the obligations of the government both at international and national levels.[84] As of 2019, the Attorney General's Office had not yet received any request relating to human rights impact evaluation of a trade agreement from the Ministry of Trade.[85] This office prioritizes examining trade agreements through the lens of the Kenyan Constitution and the country's obligations at the World Trade Organization rather than through a human

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[73] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya", *African Human Rights Law Journal*, vol. 19, No. 2 (2019), p. 716. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 (accessed 12 January 2022).

[74] Martin Mwita, "Hope for Kenya-US trade deal as ministers hold talks", *The Star* (Nairobi), 9 December 2021. Available from https://www.the-star.co.ke/business/kenya/2021-12-09-hope-for-kenyaus-trade-deal-as-ministers-hold-talks/ (accessed 22 January 2022). See also AGOA.info "US pressured over delayed promise to Kenya' in letter sent to USTR Tai" available from https://agoa.info/news/article/15880-us-pressured-over-delayed-promise-to-kenya.html (accessed 21 January 2022). The reasoning was that AGOA would expire in 2025 and Kenya needed to ensure that they maintained the "gains" obtained through AGOA.

[75] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya" *African Human Rights Law Journal*, vol. 19, No. 2 (2019),p. 716. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 (accessed 12 January 2022).

[76] Ibid., p. 716.

[77] Ibid., p. 717.

[78] Ben Sihanya, "Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya", 2005. Available from https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm.

[79] Ibid.

[80] Ibid.

[81] Ibid.

[82] Ibid.

[83] Ibid.

[84] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya", *African Human Rights Law Journal*, vol. 19, No. 2 (2019), p. 718. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 (accessed 12 January 2022).

[85] Ibid. Ogendi notes that the AGs Office relies on requests, proposals or documents presented from the Ministry of Trade. Moreover, the capacity of the AG's office in matters of human rights is low.

rights lens. The Kenya National Commission on Human Rights (KNCHR) has also not received any complaint in relation to human rights and trade.[86] KNCHR has also not, on its own volition, taken up any projects on trade and human rights in the area of pharmaceutical trade and related policies with government departments despite its mandate to advise the very same government on human rights issues.[87]

Looking at this trade policy making process, the situation seems even more concerning in the context of the negotiation objectives of both the US and Kenya in the USKEFTA which were released on 28 May 2020 and 22 June 2020 respectively.[88] The US Negotiation Objectives are heftier than the Negotiation Objectives and Principles offered by the Kenyan Government.[89] Protection of IPRs and enforcement dominates the IP section of the US Objectives; they seek to import US standards onto the Kenyan legal landscape.[90] This ramping up of the protection and enforcement of IPRs is also known as TRIPS-plus.[91] The US also aims to have the USKEFTA serve as a model for additional agreements across Africa.[92] The US Objectives make reference to the Doha Declaration stating that they aim to respect the Declaration and "ensure that the Agreement fosters innovation and promotes access to medicines, reflecting a standard similar to that found in US law".[93] It is unclear how this objective will be realized as it seems contradictory in and of itself. The US does not have a good record in its FTAs history with regards to enabling the use of TRIPS flexibilities. It has succeeded in listing conditions in FTAs, such as in the US-Jordan FTA, that make it hard to apply compulsory licensing.[94] It only partially departed from this course in the negotiations leading up to the Regional Comprehensive Economic Partnership (RCEP) where it expressly stated that the IP chapter did not and should not prevent the effective utilization of Article 31*bis*, but ultimately did not become party to RCEP.[95] The bargaining power of the region involved must be considered in weighing the predictability of this outcome in other regions. In this vein, it does not seem likely that Kenya would easily obtain this, especially because the USA was the first country to ratify the current iteration of article 31*bis*. This is evinced by the fact that the USKEFTA drifts from the TRIPS Agreement by seeking enhanced protections and in some cases limiting the application of flexibilities, which points towards

[86] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya", *African Human Rights Law Journal,* vol. 19, No. 2 (2019),p. 719. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 (accessed 12 January 2022).
[87] Ibid.
[88] Trade negotiations usually occur in secret, as such the only documentation available to the public are the respective governments' communications. For a timeline of events on the ongoing USKEFTA negotiations see CIPIT "USKEFTA Insights: Timeline", 2021. Available from https://www.theuskenyaftainsights.org/timeline?page=2.
[89] Joanna Kahumbu and others, "The Proposed US-Kenya FTA and Its Impact on Kenya's Intellectual Property Laws", 13 May 2021. Available from https://www.theuskenyaftainsights.org/article/15/The%20Proposed%20US-Kenya%20FTA%20and%20Its%20Impact%20on%20Kenya%E2%80%99s%20Intellectual%20Property%20Laws
[90] Paul Ogendi, "Future trade and investment commitments and access to medicines: US-Kenya FTA and safeguarding public health" GEGI Working Paper, No. 044, (Boston, Massachusetts, Boston University, 2021) p. 6 Available from https://www.bu.edu/gdp/files/2021/04/GEGI_WP_044_Ogendi_FIN.pdf. (accessed 21 January 2021).
[91] Carlos Correa, *Mitigating the Regulatory Constraints Imposed by Intellectual Property Rules under Free Trade Agreements*, Research Paper No. 74 (Geneva, South Centre, February 2017). Available from https://www.southcentre.int/wp-content/uploads/2017/02/RP74_Mitigating-the-Regulatory-Constraints-Imposed-by-Intellectual-Property-Rules-under-Free-Trade-Agreements_EN-1.pdf.
[92] United States, Office of the United States Trade Representative Executive Office of the President "United States -Kenya Negotiations: Summary of Specific Negotiation Objectives, (Washington, May 2020). Available from https://ustr.gov/sites/default/files/Summary_of_U.S.-Kenya_Negotiating_Objectives.pdf (accessed 10 January 2022).
[93] Ibid.
[94] Paul Ogendi, "Future trade and investment commitments and access to medicines: US-Kenya FTA and safeguarding public health" GEGI Working Paper, No 044, (Boston, Massachusetts, Boston University, 2021) p. 10 Available from https://www.bu.edu/gdp/files/2021/04/GEGI_WP_044_Ogendi_FIN.pdf (accessed 21 January 2021).
[95] Ibid.

these agreements also potentially nullifying for Kenya the waivers sought by South Africa and India with regard to COVID-19 related IPRs.

At the time of drafting this paper, the USKEFTA has since been replaced by the United States-Kenya Strategic Trade and Investment Partnership (STIP). On 14 July 2022, STIP was launched by US Trade Representative, Ambassador Katherine Tai, and Kenya's Cabinet Secretary for Industrialization, Trade and Enterprise Development, Betty Maina. STIP pursues enhanced engagement between the two governments leading to high standard commitments in a wide range of areas with a view to increasing investment and further goals.[96]

As foreshadowing to what Kenya might expect if the USKEFTA comes to fruition, the effect of TRIPS-plus provisions in FTAs is evinced by the hurdles of a recent application in the Dominican Republic to issue a compulsory license for Pfizer's COVID-19 oral antiviral candidate, Paxlovid.[97] Knowledge Ecology International (KEI) requested the grant of a government use and an open public interest license under Article 46 of the Dominican Republic Industrial Property Law to manufacture, sell, and import Paxlovid which is marketed by Pfizer in combination with ritonavir and shows promising results as a treatment against COVID-19.[98] The Dominican Republic, where Pfizer has filed a patent application for Paxlovid, is not party to an agreement which authorizes the sale of Paxlovid within 95 licensed countries or in countries where there are no granted patents or patent applications pending.[99] Article 46 of the Dominican Republic Intellectual Property Law incorporates the TRIPS flexibility of compulsory licensing by authorizing the grant of open licenses on public interest grounds.[100]

In addition to the rights and obligations created by its domestic law, the Dominican Republic has also entered into FTAs such as the US-DR-CAFTA with the US and Central American countries. Under the US-DR-CAFTA, like under numerous other FTAs the US has negotiated with developing countries, intellectual property protections are imposed which require obligations beyond those provided for in TRIPS.[101] DR-CAFTA eroded the ability of the Dominican Republic to use some of the TRIPS flexibilities because of TRIPS-plus IP protections.[102] One of such erosions is in this instance viewed through the provision for test data exclusivity for pharmaceutical products in US-DR-CAFTA.[103] This has meant that KEI has had to request the Dominican Republic to waive those provisions in the FTA with regards to the Paxlovid antiviral, and separately write to the USTR asking that they provide KEI and the Dominican Republic Government with a letter stating that it will not enforce the

[96] US – Kenya Strategic Trade and Investment Partnership, Notice and Request for Comments by USTR on 5 August 2022. Available from https://www.federalregister.gov/documents/2022/08/05/2022-16798/us-kenya-strategic-trade-and-investment-partnership (accessed 18 August 2022).
[97] BioWorld, "Promising results drive push for Paxlovid compulsory license", 7 December 2021. Available from https://www.bioworld.com/articles/514050-promising-results-drive-push-for-paxlovid-compulsory-license?v=preview.
[98] Knowledge Ecology International, "Request for a public interest license to exploit inventions relating to the COVID-19 oral antiviral Paxlovid", 3 December 2021. Available from https://www.keionline.org/wp-content/uploads/Request-Compulsory-License-Dominican-Republic-EN-3Dec2021.pdf.
[99] Knowledge Ecology International, "KEI requests an open compulsory license relating to Paxlovid in the Dominican Republic", 6 December 2021. Available from https://www.keionline.org/37066.
[100] It is worth noting that the use of the word 'shall' in article 46 couches the granting of a public interest license in mandatory terms. The Dominican Republic Industrial Property Law came into force and was created pursuant to the country adapting its legislation to align with the provisions of TRIPS. See Preamble and Article 46, Industrial Property Law of the Dominican Republic, (2000).
[101] Georgetown University Law Centre, Human Rights Institute, "Prescription for Failure: Health & Intellectual Property in the Dominican Republic", 2010. Available from https://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1004&context=hri_papers.
[102] Ibid.
[103] Article 15.10, US-DR-CAFTA, (2004).

test data provisions.[104] This situation throws into stark relief the virtual inability of the Dominican Republic to utilize TRIPS flexibilities as a result of TRIPS-plus incorporations in FTAs. At the time of drafting this paper, Pfizer has opposed KEI's request for the license and demanded the Dominican Republic patent office to schedule a hearing to mediate.[105]

Although the Dominican Republic and Kenya's compulsory licensing provisions within their national legislations align with the spirit of the Doha Declaration, echoing the intentions and efforts of the Global South with regard to access to medicines and the public interest, this could be potentially hindered by TRIPS-plus provisions in FTAs (such as data exclusivity and "patent linkage") that prove to be obstacles in furthering access to medicines in the Global South. It is with this in mind that efforts to ramp up the resistance to TRIPS-plus provisions in FTAs that hinder the overall spirit of the Doha Declaration should be considered.

d) Resistance to TRIPS-Plus Provisions

Although developing and least developed countries have been very vocal at the WTO about the Doha Declaration, when it comes to bilateral agreements, there is not much coordination to resist TRIPS-plus provisions. In a rare occasion Southern Africa, via the Southern African Customs Union, seems to be the only African region to have left a potential US FTA on the table.[106] Moreover, it has been argued that the influence of the Doha Declaration is waning in Kenya.[107] Trade policymakers are usually more assertive away from home in international arenas but do not follow up by implementing these assertive stances at home.[108] Although Kenya's Principal Secretary at the State Department for Trade and Enterprise faulted countries in the Global South for the ongoing vaccine inequity, he went further to say that the challenge was not the pharmaceutical companies still in opposition to the waiver but the value chain.[109] Nevertheless, Kenya still joined South Africa and India in seeking the TRIPS waiver at the WTO.[110] The true test of Kenya's resistance to TRIPS-plus provisions will be the resultant text of the USKEFTA if it should come to completion. Kenya should also consider that its negotiating strategy should envision what the agreed terms would mean for other countries in the region. At the time of drafting this paper, Kenya and the US were still negotiating their FTA but not much information is coming forth on the state of these negotiations; it seems that the Kenyan delegation is awaiting action from the US delegation which does not bode well. Further, if the United Kingdom-Kenya Economic Partnership Agreement[111] is an indication of how the details of such an agreement will be presented to members of the public through their representatives in Parliament, there is much left to be desired. The Ministry of Trade in this instance and the relevant Trade Committee did not submit relevant information that could have allowed these members to make an informed

[104] Knowledge Ecology International, "KEI requests an open compulsory license relating to Paxlovid in the Dominican Republic", 6 December 2021. Available from https://www.keionline.org/37066.
[105] Article 43(5), Industrial Property Law of the Dominican Republic, (2000).
[106] Bilaterals, "US-SACU", May 2012, Available from https://www.bilaterals.org/?-us-sacu-.
[107] Paul O. Ogendi, "Pharmaceutical trade policies and access to medicines in Kenya" (2019) *African Human Rights Law Journal*, vol. 19, No. 2 (2019), p. 717. Available from http:/dx.doi.org/10.17159/1996-2096/2019/v19n2a7 (accessed 12 January 2022).
[108] Ibid.
[109] Luke Anami, "Kenya upset over stalled talks on jab IP rights", *The Nation* (Nairobi), 28 October 2021. Available from https://www.theeastafrican.co.ke/tea/business/kenya-upset-over-stalled-talks-on-jab-ip-rights-3599064.
[110] World Trade Organization, "Members discuss TRIPS waiver request, exchange views on IP role amid a pandemic", 25 February 2021. Available from https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm.
[111] British High Commission in Kenya "UK-Kenya Economic Partnership Agreement enters into force", 24 March 2021, available from https://www.gov.uk/government/news/uk-kenya-economic-partnership-agreement-enters-into-force.

decision as to the ratification of the agreement pursuant to the requirements for public participation envisioned by the Kenyan Constitution.

4. "RE-IMAGINING" ARTICLE 31*BIS* IN LIGHT OF THE CURRENT TRIPS WAIVER

a) How a Global South Perspective Maintains the Spirit of the Doha Declaration

The Doha Declaration affirmed Members' right to protect public health and promote access to medicines for all; the push for a waiver to this effect was largely driven by the efforts of countries in the Global South. The African Group and its supporters were primarily seeking clarification that nothing in TRIPS should prevent countries from exporting generic drugs to poor countries.[112] Beginning as early as 1998, numerous non-governmental organizations expressed concerns that implementation of TRIPS could in fact be deleterious to the protection of public health in poor countries.[113] When a special discussion on intellectual property and access to medicines was held by the TRIPS Council in 2001 at the request of the African Group, the need to clarify the flexibilities available under TRIPS and to establish the relationship between IPRs and access to medicines was paramount.[114] Key issues identified by the African Group, of which Kenya has been a leader, were firstly that article 31(f) of TRIPS restricted the use of compulsory licensing for supply outside domestic markets which disadvantaged countries with insufficient manufacturing capacity from making any meaningful use of the flexibility.[115] Secondly, the Group demanded a wider approach to creating a solution and an interpretation of the effective use of compulsory licensing that took into consideration the needs of Members.[116] Thirdly, Kenya argued that article 31(f) of TRIPS should be deleted or amended as it was unworkable.[117]

The essence of the Doha Declaration was the proposition by developing countries in their draft that "nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health." After "full of conditionalities" were inserted and the Paragraph 6 solution was reached in 2003, the African Group tabled a proposal suggesting a straightforward translation of the same into an amendment of Article 31.[118] This proposal with the key issues raised by the African Group is what the final result should have been, as opposed to the iteration of article 31*bis* that was eventually included.

The attempt at adopting a new waiver of TRIPS implies a recognition that the existing TRIPS flexibilities, even those affirmed by the Declaration, were incapable of rapidly addressing the present pandemic.[119] The motivations behind both the 2001 and 2020 proposals for a waiver to TRIPS remained the same, indicating that promoting and protecting access to

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[112] Susan K. Sell, "TRIPS and the Access to Medicines Campaign", *Wisconsin International Law Journal*, vol. 20, issue 3 (2001).
[113] Ibid.
[114] Haochen Sun, "The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health", *European Journal of International Law*, vol. 15, no. 1 (2004).
[115] Ben Sihanya, "Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya", 2005, available from https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm.
[116] Ibid.
[117] Ibid.
[118] Oxfam, "Africa and the Doha Round", available from https://oxfamilibrary.openrepository.com/bitstream/handle/10546/114077/bp80-africa-doha-091105-en.pdf?sequence=1&isAllowed=y.
[119] Siva Thambisetty, Aisling McMahon, Luke McDonagh, Hyo Yoon Kang, Graham Dutfield, "The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic", LSE Legal Studies Working Paper No. 06/2021 (London, England, LSE, 2021) available from https://deliverypdf.ssrn.com/delivery.php?ID=666112089118089005106080090109110066019041046044086035108096075122066102025087110113031012096001011007032119012126092096066125121055070011022074031098112004066075077058037092123024024072112064002070017031119016074027015108005075112028012072015119086&EXT=pdf&INDEX=TRUE.

pharmaceuticals is at the forefront of the developing worlds' agenda when it comes to IPRs and public health. This agenda ought to find reflection in any future reiteration of article 31*bis* if such a future exists.

b) Does the Global South Need to Reconsider How it Engages at the WTO?

Public health, even amidst a global pandemic, does not seem to sway the Global North countries into considering the flexibilities already won, let alone new flexibilities sought.[120] The situation can be argued to be worse than the conditions that pushed the Doha Declaration forward. The opposition to the waiver should be viewed as a warning sign for negotiations at the WTO, going forward. What these countries ought to consider with the lens of human rights, as encompassed also in the modern development theory, is what ought to be done going forward to ensure that they meet their obligations regarding the right to health at the highest attainable standard for their citizens, while attaining socio-economic progress.

[120] Luis Gil Abinader, "Bolivia seeks to import COVID-19 vaccines from Biolyse, if Canada grants them a compulsory license", Knowledge Ecology International, 11 May 2021. Available from https://www.keionline.org/36119. Luis argues that "Canada cannot continue to claim that article 31bis of the TRIPS agreement functions "as intended" while it stonewalls a legitimate attempt to use this mechanism." The success of this attempt depends on the reluctant Canadian Government.

5. CONCLUSION

When history repeats itself, we ought to take heed of the lesson mastered from the similar set of circumstances. The need for the new requested TRIPS waiver is an indication that the aims of the Doha Declaration have not been met. The success of a waiver applicable to vaccines, treatments and diagnostics is also in question, as it faces a great amount of resistance mostly from developed country members at the WTO, who use justifications based on theories of intellectual property that do not align with the human rights obligations of countries. While developing and least developed countries provide a strong front together at the multilateral arena, this trend is not observed when considering bilateral agreements. In order to ensure that these countries are not caught in a constant loop of seeking waivers at the WTO we recommend the following:

- The governments of these countries ought to invest in promoting a human rights-based approach in their trade policy making. This would require that the personnel in the various departments that deal with international trade are introduced to aspects of human rights that relate especially to the right to health.

- Public consultation should be considered before adopting the final texts of FTAs between developing and developed countries with a history of TRIPS-plus provisions in their bilateral agreements. This would assist to bridge the knowledge gap by allowing those with the skills to comment.

- The trade negotiators should always enter into negotiations of bilateral agreements with the knowledge that the flexibilities encompassed within the TRIPS Agreement are cumbersome to apply and any further derogation of these flexibilities within these agreements would make an already untenable situation impossible.

Finally, the imbalance in bargaining power of individual countries negotiating FTAs with countries in the Global North ought to be carefully re-evaluated considering not only the development goals of countries in the Global South, but also the concerted efforts being made to promote regional integration. Countries in the Global South that are members of regional trade agreements, such as Kenya's involvement in the East African Community Customs Union and the African Continental Free Trade Area, makes it incumbent upon them to negotiate trade agreements with third parties as a unified bloc if and when such regional negotiation is in the interest of, and likely to benefit, other members of the regional schemes. This would significantly improve their bargaining power in rejecting terms in FTAs that do not align with their agendas, as well as to empower them to reject entire agreements when appropriate.

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